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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,383	09/18/2001	Neng-Yang Shih	AL01019	8337

24265 7590 08/29/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/29/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/955,383

Applicant(s)

SHIH ET AL.

Examiner

Hong Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-10, 13 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) 5, 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4, 6, 7, 10 and 13, 18-21 is/are rejected.
- 7) ☐ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10, 13, and 15-21 are pending in this application.

This action is in response to the applicants' amendment and reply filed on June 30, 2003.

Response to Arguments

Applicants' arguments and amendments filed on June 30, 2003 have been fully considered but they are not persuasive. Rejections of Claims under 35 U.S.C. 112, first paragraph are maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicants' election of Group I subject matter with traverse is noted but is not found to be persuasive for the following reasons. Restriction is proper when there is a lack of unity of invention and such is not affected by the manner of claiming-i.e. in separate claims or within a single claim. As stated in the previous action the resultant compounds embraced by formula II and formula III are structurally dissimilar compounds. Placing all such compounds into the same claim is repugnant to scientific classification as they are separately classified and require separate literature searches. As indicated in the previous office action, each of the groups belong to a separate class and numerous subclasses. To search all the patents under these classes and subclasses would place a substantial burden on the examiner, let alone search of other non-patent literature. Having a common utility among the groups is not enough where as herein there is not a substantial structure feature common to all groups. They are made and used independently of each other, are not art-recognized equivalents. Such traverse of the restriction requirement is not

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consistent with applicants' urging of patentability over the art cited below which is much closer to some of the claimed compounds than they in turn are to each other.

For the above reasons, the restriction is still deemed proper and is therefore made FINAL.

Claims 1, 16, and 17 are objected to as being an improper Markush grouping. The recited compounds, while possessing a common utility, present a variable core and, thus, the Markush groups represented by the term where X and Y are both carbon and the term where one of X or Y is carbon and the other is nitrogen have variably different definitions, rendering the claims clearly improper.

Deletion of non-elected subject matter would overcome this objection.

New Matter

The amendments filed on June 30, 2002 are objected to under 35 U.S.C. 132 because they introduced new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Z¹ in claims 1 and 19-21 which is not disclosed in the original specification. Clarification is required.

Claim Rejections - 35 USC § 112

Claims 1-4, 6, 7, 10, 13, 15 and 18 remain rejected and claims 19-21 are rejected under 35 U.S.C. 112, first paragraph, for reasons already made of record notwithstanding applicants' traverse. The examiner in this case has provided both "evidence" and "reasoning" to cast doubt on the sufficiency of enablement provided in the instant closure. See rejection made in the previous office and those maintained below.

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The claims are still not commensurate in scope as to the diversity of Markush groups of variable M, which, in addition to being a piperidine or piperazine, can be any 4-, 5-, 6-, 7-, or 8-membered saturated heterocycle. The instant case is similar to *In re Lund*, 153 USPQ 625, in which the Court agreed the specific aldehyde reactants mentioned in the specification fell within a limited range and thus far short of the claims' scope. In view of applicants' intention in the amendments to cover piperazine, piperidine, and pyrroliline, further amendments to limit M to these species will be acceptable.

Claims 13, 15, and 18 remain rejected under 35 U.S.C. 112, first paragraph for reasons already made of record and notwithstanding applicants' traverse. These method claims remain non-enabled based solely on histamine receptor antagonistic activity relied on herein. Contrary to what applicants urge is enabled, there is no art-recognized evidence of clinical efficacy for the scope being claimed, and applicants have not provided any adequate traversal to refute the argument made by the examiner. As was previously mentioned in the last office action, Leurs and Timmerman's article shows that H3-receptor antagonists are mainly useful for treatment of airway and gastrointestinal disorders. The Stark reference submitted by applicants only "proposed" several therapeutic indications for H3 receptor antagonists. In the absence of experimental evidence showing a nexus between H3 receptor antagonism and the effective treatment of all diseases associated with this specific mode of action, the method of treating all diseases apparently contemplated and associated with these antagonists has not been enabled. Note the new utility guidelines stress that tests relied on must be recognized by those skilled in the art as reasonably predicative of in vivo efficacy in man the intended host. Note the remarks made in the recent decision , *Genetech V. Novo Nordisk* 42 USPQ2d 1001 for compliance with

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35 U.S.C. 112, par. one., "This specification provides only a starting point, a direction, a direction for further research." while a different fact situation existed in that case the wording is appropriate herein.

The rejections of claims 1, 11, 12, 14, 16, and 17 under 35 U.S.C. 112, second paragraph, are hereby withdrawn in view of applicants' amendments.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for official business is (703) 308-4556. Any inquiry of a general nature or relating to the

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status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl

August 27, 2003


Mukund Shah
Supervisory Patent Examiner
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